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Country Market Survey

Medical Equipment

Italy

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Italy

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The market for medical equipment in Italy, spurred by the Health Reform Act of 1982, is projected to expand an average 6 percent annually to $554 million[1] in 1988 (see table 1). The extension and modernization of medical treatment has been sparked by the following developments:

- The entire population of Italy (56.7 million) came under health insurance coverage in 1982.
- The number of physicians is expected to increase from 164,555 in 1980 to 230,347 in 1985.
- Strong demand for an efficient public health service, particularly in the less advanced southern regions, continues to grow.
- Government officials plan to reallocate financial resources to equalize health facilities throughout the country.
- National health plans call for higher quality health care, better training of personnel, and integration of health and social welfare services.

[1] All values are given in U.S. dollars. Local currency is converted at the following exchange rates: US$1 = 1,136.7 lire (1981), and 1,352.5 lire (1982, and subsequent years). Values for 1983 and later years are given in 1982 constant dollars.

Table 1.—Italy: Domestic production, imports, exports, and apparent domestic consumption of medical equipment, 1981-82 and 1988
(in millions of U.S. dollars)

	1981	1982	Projected 1988
Medical/surgical, electromedical, diagnostic, ophthalmic apparatus (90.17)			
Domestic production	131.89	122.07	137.3
Imports	238.39	231.61	355.9
Exports	111.04	103.01	109.3
Domestic consumption	259.24	250.67	383.9
Mechanotherapy and respiratory appliances (90.18)			
Domestic production	9.71	9.16	10.4
Imports	9.10	6.90	7.2
Exports	8.41	6.84	6.5
Domestic consumption	10.40	9.22	11.1
Orthopedic appliances, prostheses, hearing aids, pacemakers, etc. (90.19)			
Domestic production	30.35	29.31	37.1
Imports	41.74	47.59	63.1
Exports	15.99	17.03	20.2
Domestic consumption	56.10	59.87	80.0
X-ray apparatus (90.20)			
Domestic production	70.83	67.26	68.7
Imports	56.04	54.64	61.9
Exports	63.17	51.61	51.7
Domestic consumption	63.70	70.29	78.9
Combined total			
Domestic production	242.78	227.80	253.5
Imports	345.27	340.74	488.1
Exports	198.61	178.49	187.7
Domestic consumption	389.44	390.05	553.9

Source: Annual foreign trade statistic from ISTAT (Central Italian Data Institute) and International Trade Administration research report, "Profile of Medical Equipment Market—Italy" (see Additional Information box).

The commitment of resources to upgrade the health care sector affords U.S. producers of high-technology equipment excellent sales opportunities (see tables 2 and 3). Ultrasonic equipment is showing the fastest market expansion. Manufacturers of nuclear diagnostic equipment and sophisticated replacements for implantable pacemakers can look forward to a brisk rise in sales. High sustained growth in demand for technologically advanced cardiology equipment is anticipated, while a moderate, steady rate of advance is foreseen for dialysis equipment. Little change has been projected in the markets for neurological, pulmonary, or operating room equipment.

Competitive Assessment

Imports, amounting to $340 million in 1982, supply a major share of the $390 million domestic market as well as essential components for Italian exports of medical equipment. Imports are concentrated on the high-technology end of medical equipment including

Table 2.—Italy: Imports of medical equipment by country of origin, 1982-83 and 1988
(in millions of U.S. dollars)

	1982	1983	Projected 1988
Medical/surgical, electromedical, diagnostic, ophthalmic apparatus (90.17)			
United States	43.63	37.38	99.0
Germany	49.22	47.20	
France	24.89	26.24	
Japan	19.26	24.79	
Netherlands	15.21	15.62	
Others	79.40	83.11	256.9
Total	231.61	234.34	355.9
Mechanotherapy and respiratory appliances (90.18)			
United States	1.93	1.62	2.0
Germany	1.71	1.85	
Others	3.26	3.88	5.2
Total	6.90	7.35	7.2
Orthopedic, prosthetic appliances (90.19)			
United States	10.95	9.80	14.0
Germany	6.32	5.73	
Switzerland	7.35	8.26	
Netherlands	9.00	8.12	
Others	13.97	12.87	49.1
Total	47.59	44.78	63.1
X-ray apparatus (90.20)			
United States	6.84	3.44	6.2
Germany	22.06	20.42	
Netherlands	6.37	11.00	
France	10.19	7.06	
Others	9.18	9.32	55.7
Total	54.64	51.24	61.9
Combined total			
United States	63.35	52.24	121.2
Germany	79.31	75.20	
Others	198.08	210.27	366.9
Total	340.74	337.71	488.1

Source: ISTAT and International Trade Administration research report.

Table 3.—Italy: Sales outlook for specific U.S.-made medical equipment and major competitors, 1984-88

Items	Current level	US sales outlook	Major competition Country	Major competition Company
Cardiology equipment				
Central station intensive care systems	Good	High	Germany	Siemens A.G.
			Japan	Nihon Kohden, Tomioka Co. L.d.t.
Computer system for ECG recordkeeping	Medium	High	Germany	Siemens A.G.
Defibrillators	Medium	Medium	Netherlands	Philips N.V.
			Germany	Siemens A.G.
			Denmark	Simonsen and Weel (Medico Teknik S.A.)
Ultrasonic cardiology equipment	High	Good	Japan	Toshiba Medical System
			Japan	Aloka L.d.t.
Electrocardiographs	Low	Medium	Germany	Siemens A.G.
			Italy	Remco Italia
			Italy	OTE Biomedica
ECG, portable (Holter Monitor)	High	Medium	Germany	Siemens A.G.
			Italy	Remco Italia
Telemetry system for transmitting electrocardiograms	Fair	Good	Germany	Siemens A.G.
			Japan	Fukuda L.d.t.
Intracardiac catheters	Fair	Fair	Germany	Siemens A.G.
Cardioversion systems consisting of defribrillator recorder, oscilloscope, and amplifier	Fair	Good	Germany	Siemens A.G.
Operating room equipment				
Electrosurgical units	Good	Good	Italy	Danieli
			Germany	Martin
Endoscopy equipment	Medium	Medium	Germany	Siemens A.G.
Surgical lighting	Good	Good	Germany	Siemens A.G.
			Japan	Scialux L.d.t.
Electric suction devices for surgery	Low	Medium	Germany	Siemens A.G.
Anesthetic gas evacuation system	Low	Good	U.K.	Howrth
Pediatric equipment				
Infant intensive care monitors	Medium	Good	Japan	Nihon Kohden Tomioka
Ultrasonic diagnostic equipment	Good	Good	Japan	Aloka
			Japan	Toshiba Medical
General hospital equipment				
Ultrasonic scanners	High	High	Japan	Toshiba Medical System
			Japan	Aloka L.d.t.
			Japan	Hitachi
			Netherlands	Philips N.V.
			Germany	Siemens A.G.
Ultrasonic physiotherapy equipment	High	High	Japan	Aloka L.d.t.
			Japan	Toshiba Medical System
Central station patient monitoring systems	Medium	High	Japan	Nihon Kohden Tomioka Co. L.d.t.
			Germany	Siemens A.G.
			Italy	Kontron
Bedside patient monitoring systems	Medium	High	Germany	Siemens A.G.
			Japan	Nihon-Kohden Tomioka Co. L.d.t.
Computerized axial tomographic	Low	Medium	Germany	Siemens A.G.
			Netherlands	Philips N.V.
			Japan	Toshiba Medical System
Nuclear magnetic resonance scanners	Low	Medium	Netherlands	Philips N.V.
Gamma cameras	Low	Medium	Netherlands	Philips N.V.
			Japan	Toshiba Medical System
Clinical laboratory equipment				
Infusion pumps	Medium	High	Germany	Braun
Atomic absorption	Good	Good	Netherlands	Philips N.V.
Automatic analyzers	Good	Good	Japan	Shimadzu L.d.t.
Gas chromatographs	Good	Good	Japan	Shimadzu L.d.t.
			Netherlands	Philips N.V.
Spectrophotometers	Good	Good	Japan	Shimadzu L.d.t.
			Netherlands	Philips N.V.
			Finland	Kone Oy
Spectrofluorometers	Good	Good	Japan	Shimadzu L.d.t.
Radioimmunassay systems (RIA)	High	High	Switzerland	Beckman Instruments
Electrophoresis systems	Fair	Medium	Japan	Olympus Optical Co.
Renal equipment				
Disposable dialyzers	Good	Good	Sweden	Gambro

Table 3.—Italy: Sales outlook for specific U.S.-made medical equipment and major competitors, 1984-88—continued

Items	Current level	US sales outlook	Major competition Country	Major competition Company
Ophthalmological equipment				
Refraction unit with split lamp, ophthalmometer, vision tester	Fair	Fair	Japan	Topcon L.d.t.
Neurological equipment				
Electromyographs	Fair	Medium	United Kingdom	Medelec L.d.t.
Orthopedic and prosthetic equipment				
Artificial organs, pacemakers implantable	High	High	Italy	Sorin-Biomedica
			Germany	Siemens A.G.
Hearing aids	Low	Low	Italy	Mercury Acusticon
			Denmark	Oticon
Orthopedic appliances	Medium	Good	Switzerland	Protek A.G.
			Germany	Waldemar Link Gmbh
Hip replacement with acetabular curs, knee replacement and elbow replacement	Medium	Good	Switzerland	Protek A.G.
			Switzerland	Osteo A.G.

Source: International Trade Administration research report.

Table 4.—Italy: Health care expenditures in relation to GNP and budget, 1981-82 and 1988

(in millions of U.S. dollars)

	1981	1982	Projected 1988
Public sector			
Total government budget	123,960	122,718	138,300
Budget for health care	20,642	20,422	23,000
Capital expenditures	484	296	520
Services	18,322	18,588	22,100
Private sector			
Estimate of total private expenditure on health care	3,100	3,000	3,500
Gross national product	353,040	347,355	369,685
% of Government health care budget to GNP	5.8	5.9	6.2
% of total public and private health care expenditures to GNP	6.7	6.7	7.2
Per capita GNP	6,244	6,121	
Per capita private health care expenditure	54	52	

Source: ISTAT (Yearbook 1983) and International Trade Administration research report.

very sophisticated diagnostic and monitoring instrumentation. European and Japanese firms accounted for three-fourths of import sales in 1982 compared with the 15-percent share provided by U.S. firms. These proportions are expected to alter slightly through the end of the decade, with U.S. sales climbing as health care providers seek more sophisticated equipment. German manufacturers, currently leading with about 22 percent of the import market, are well positioned to capitalize on this rising market. Firms from other Western European countries such as France and Switzerland are likely to provide lively competition. Japanese suppliers have made inroads in the market, but remain well behind major European exporters and U.S. firms which have kept their second-place position despite higher dollar values.

Domestic production is expected to keep pace with the market throughout the 1980's. The 55 local manufacturers, with a total work force of 3,600, specialize in medium-level technology at contained prices and have nurtured a special sales position with the small State and private hospitals. Their major products are dialysis apparatus, conventional X-ray diagnostic equipment, implantable pacemakers, cardiology equipment, anesthesia apparatus, and such operating room equipment as surgical tables.

Subsidiaries of multinational corporations (e.g., Siemens, Germany; Philips, Netherlands; and CGR, France) manufacture high-technology X-ray diagnostic equipment. Over 75 percent of Italian output is exported, primarily to the developing countries.

Health Care Systems

Public responsibility for health care in Italy was formally established in 1978 with the creation of a national health service. The administration of public health is centralized under SAUB (Basic Unified Administrative Structure). Decisions on major health care policies and investment priorities for medical equipment and plant are made by the Health Ministry and National Healthcare Council.

The Health Ministry, charged with developing programs, designed a long-term National Healthcare Plan and is responsible for the size and character of the national health care fund. The Ministry issues decrees, makes spending decisions, draws up contracts with health care providers, and coordinates the national health system.

The National Health Council prepares regular reports on the status of Italian health care and makes recommendations on health care policy to the Government. These recommendations have included distribution of national health care funds, suggestions for contracts between Local Health Care Units (USL) of the Government and rehabilitation institutes, detailed requirements for laboratory diagnostic institutions, and drugs eligible for government subsidy. The Council, not yet fully operational, is likely to wield greater power as its organization develops.

The Reform Act sought to decentralize health care administration by setting up Regional Health Ministers (Assessorati) with legislative and management powers to be exercised under national guidelines. The Regional Minister for Health and Hygiene makes the decisions to establish facilities and purchase medical equipment. USL's are to be constructed within each region as centers for the actual delivery of health care services. Quite a few local units have yet to be established.

The effort by national authorities to contain deficits and control costs as the public health sector expands is reflected in modest projected increases for the overall health budget through 1988 (see table 4). Capital expenditures, however, are scheduled to rise by nearly 10 percent annually between 1982 and 1988.

General hospitals should continue to account for 65 percent of the purchase of medical equipment through 1988 (see table 5). University medical centers and specialized institutions, such as cancer clinics, together account for roughly 17 percent.

Sixty percent of the 1,826 hospitals in Italy have 200 or fewer beds, while 85, not quite 5 percent, have more than 1,000 (see table 6). Of the 10 million patients hospitalized in 1981, the largest numbers were in obstetric, orthopedic, accident, pediatric, and general medical-surgical units.

Table 5.—Italy: Estimated expenditures for medical equipment by major user sectors, 1982 and 1988

(in millions of U.S. dollars)

	1982		Projected 1988	
	Equipment	Supplies	Equipment	Supplies
General hospitals	235	780	344	900
University medical centers	31	75	42	90
Specialized medical institutions	33	110	50	150
Military hospitals	1	35	1	35
Clinical laboratories	18	22	21	25
Mobile and permanent health care/population screening centers	15	22	21	24
Physicians (private practitioners)	34	65	52	76
Total	367	1,109	531	1,300

Source: International Trade Administration research report.

Table 6.—Italy: Number of hospitals and beds by category, 1981

	Hospitals	Beds
Public-sector hospitals		
General		
Regional	59	98,115
Provincial	200	133,128
Zone and dispensaries	608	125,412
Total	867	356,655
Specialized		
Regional	35	15,753
Provincial	113	27,319
Zone and dispensaries	36	3,820
Total	184	46,892
Psychiatric hospitals	96	47,871
Total	**1,147**	**451,418**
Private-sector hospitals		
General	478	43,257
Specialized	111	12,641
Psychiatric	90	21,905
Total	**679**	**77,803**
Total	1,826	529,221

Source: ISTAT 1983 yearbooks.

Although 30 hospitals are equipped to perform open-heart surgery in Italy, in 1983 an estimated 6,000 patients out of a total of 18,000 (sufferers of both cardiovascular problems and congenital heart defects) underwent such operations abroad (mainly in the United States, Great Britain, Switzerland, and France) because of long waiting lists that could have delayed treatment for up to 2 years. The Italian Government, in compliance with EEC regulations, refunds patients' medical expenses incurred abroad or reimburses costs to foreign hospitals.

A new cardiovascular clinic, the Heart Center S.P.A., is being established by the Mercy Hospital Medical Center of Des Moines (Iowa), Heart International, a foundation registered in Geneva (Switzerland), and private U.S. investors. The Center will be equipped to perform heart surgery and serve as a training center for medical personnel, including nationals from third-world countries. The University of Rome has lent support to this project and will transfer four units of its cardiovascular school to the training center. The hospital plans to have 50 beds for private patients and 50 beds for public admissions.

About 15 percent of available hospital beds are located in private hospitals, which are divided into two main categories: facilities associated with the Italian Private Hospital Association (AIOP) and church-run facilities represented by the Association of Religious Social Welfare and Health Care Institutes. Clinic directors or medical directors, normally highly experienced and well-known physicians, make purchasing decisions for medical equipment. Regional governments make per diem payments to private hospitals on behalf of national health insurance patients, but these payments are lower than those extended to public hospitals.

Major Italian insurance companies have begun to sell private medical insurance policies for treatment in private sector facilities. These policies are expected to attract purchasers, because the private health care sector can provide treatment with greater speed and personal attention than the public sector.

Despite population increases, high medical school enrollments are expected to lower the doctor/inhabitant ratio from 1 to every 346 persons in 1980 to 1 physician per 215 inhabitants in 1985. Italian medical practice appears to be equally divided between specialists and general practitioners. Some 328,150 general and skilled nurses ministered to hospital patients in 1981, and the supply of medical technicians totaled 28,000.

Marketing Access

Large foreign medical equipment firms sell products in Italy through the branches of their own organizations within the country. Smaller companies find independent distribution organizations to represent them.

The key sales factor for foreign firms is aftersales service—qualified technical assistance and ensured availability of parts. In addition, health care purchasers look for quality, performance, and technological innovation in deciding to buy a piece of equipment. Price is also a factor, but always in relation to quality and performance. Consideration may also be given, in the case of public hospitals, to whether the foreign supplier will accept payment terms of 1 year or more. Relatively little weight is given to delivery times, especially for long-planned sophisticated equipment purchases. Private sector buyers place greater emphasis on price in equipment purchase decisions and settle their accounts promptly.

U.S. firms may find it profitable to exhibit medical equipment at the specialized trade fairs held in Italy throughout the year.

Trade Regulations

Medical equipment imports are governed by international trade regulations, and no barriers, restrictions, or official authorizations limit sales. Duties on equipment from the United States range from 5.6 to 6.7 percent.

Technical Requirements

Various types of standards apply to medical equipment, with different levels of legal recognition:

- Obligatory standards developed by public bodies or associations given specific legal status. Medical equipment is handled by the Comitato Elettrotecnico Italiano (Italian Electrical and Technical Committee), Technical Committee 62. So far, various standards have been issued for X-ray diagnostic equipment, and general safety standards have been established for electromedical equipment.
- Standards issued by the National Research Council, which can be defined as "rules of the art" or "good technical practices," developed on the basis of a pool of knowledge and experience and issued by organizations vested with this responsibility by law.
- Standards developed by international bodies such as IEC and ISO, which are given considerable importance in Italy.

In the absence of precise technical standards, standards developed in other countries, and particularly those in force in the more technologically advanced nations, are recognized. Equipment that conforms to U.S. standards thus will usually be acceptable in Italy.

Additional Information

The project officer responsible for Country Market Surveys on medical equipment is:

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The Survey summarizes a 64-page research report prepared by Directa Srl, under contract for the U.S. Department of Commerce, and reflects the opinions and views of interviewees in Italy and not those of the Department of Commerce. The research report gives considerably more detail on all the points touched upon in the Survey, as well as marketing practices, trade regulations, technical standards, and the names and addresses of prospective customers, potential agents and distributors, trade associations, and trade publications.

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